

## REMARKS

Claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141, and 143-189 are pending and under examination. Claims 1, 65, 90 and 144 have been amended. Support for the amendments can be found throughout the specification and the claims as filed. In particular, support for the amendment to claims 1, 65, 90 and 144 can be found, for example, on page 50, lines 5-11. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Applicants appreciate Examiner Agrawal's time and helpful discussion with Applicants' representative in the telephonic interview on June 27, 2007. During the interview, issues relating to the outstanding rejections were discussed. It is believed that the present response addresses the issues discussed during the interview.

### Objection to the Specification

The Office Action indicates that the specification contains the trademark "Windows" and is not properly identified in the specification as a trademark. The specification has been amended on page 126 to indicate that the terms "Windows" and "Macintosh" are trademarks by all capitalization, as requested in the Office Action. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

### Rejections Under 35 U.S.C. § 101 and 112, First Paragraph

The rejection of claims 1, 6-9, 11, 13, 15, 65, 70-79, 90, 95-103, 141, 143-152 and 154-189 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter is respectfully traversed. Applicants respectfully maintain, for the reasons of record, that the claimed methods are directed to statutory subject matter. Nevertheless, to further prosecution, claims 1, 65, 90 and 144 have been amended, as discussed with Examiner Agrawal, to recite the step of providing an output to a user.

Regarding the assertion in the Office Action on page 6, Applicants respectfully disagree with the assertion that a "computer readable medium is reasonably interpreted to include carrier waves." The specification teaches that the invention provides both a computer-readable medium

and a carrier wave (page 124, lines 4-18). Furthermore, MPEP §2106.1 states “[W]hen nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal...” Thus, MPEP §2106.1 clearly indicates that a computer-readable medium and an electromagnetic carrier signal (carrier wave) are considered to be alternative mediums. Applicants respectfully submit that both the computer readable medium and the carrier wave should be considered statutory subject matter.

Applicants respectfully submit that the claimed methods are directed to statutory subject matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 143-189 under 35 U.S.C. § 101 and § 112, first paragraph, as allegedly lacking a specific, substantial and credible asserted utility or a well established utility is respectfully traversed. Applicants respectfully maintain, for the reasons of record, that the claims have specific, substantial and credible utility. As suggested by Examiner Agrawal, Applicants point out that the specification teaches that the methods can be used to diagnose or determine the prognosis of a disease such as cancer, cardiovascular disease, respiratory disease, gastrointestinal disease, renal disease, metabolic disease including diabetes, immune system disease, and additional diseases (page 9, line 13, to page 10, line 2; and page 113, line 23, to page 114, line 10). As discussed in the telephonic interview with Examiner Agrawal, the specification does not merely reference a general utility but, rather, teaches a specific, substantial and credible utility, including exemplary disease for which the methods can be used. Accordingly, Applicants respectfully maintain that the claims have a specific, substantial and credible utility and request that these rejections under §101 and 112 be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 90, 95-104, 144-152 and 172-189 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description is respectfully traversed. Applicants respectfully submit that the specification provides sufficient description and guidance for the claimed methods.

Applicants respectfully submit that the specification provides sufficient description and guidance for the claimed methods of diagnosing a health state of an individual. The specification teaches that an individual having expression levels of molecules that fall within a health-associated reference expression region is predicted to have a health state similar to the reference population, which, in the case where the reference population is healthy individuals, the individual is diagnosed as being healthy (page 11, lines 21-26). The specification additionally teaches that an individual having molecules with expression levels outside the health-associated reference region has a perturbed health state, which can be correlated with a particular disease (page 11, lines 26-29). The specification additionally teaches that an expression profile of an individual can be correlated with the health state of an individual, including whether an individual is healthy, has a disease, or has a predisposition to developing a disease (page 9, lines 13-17, and page 11, lines 5-8) as well as exemplary diseases, as discussed above (page 9, line 18, to page 10, line 2; page 113, line 23, to page 114, line 10). The specification also teaches criteria for identifying a suitable reference individual and reference population (page 22, lines 16-25; page 70, line 1, to page 74, line 16), as well as statistical methods for determining whether the expression level of a molecule or molecules fall within or outside the health-associated reference expression region of a reference population (page 39, line 22, to page 44, line 26). Accordingly, Applicants respectfully submit, contrary to the assertion in the Office Action, that the specification provides sufficient description and guidance for the claimed methods of diagnosing a health state in an individual. Therefore, Applicants respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 90, 95-104, 144-152 and 172-189 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. Applicants respectfully submit that the claims are clear and definite and that it would be clear to one skilled in the art that the reference in the claims to “health state” and “individual” refers to the individual for which the health state is being diagnosed. Nevertheless, to further prosecution, claims 90 and 144 have been amended to more clearly indicate antecedent basis in the claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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